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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,649	09/29/2005	Yechezkel Barenholz	BARENHOLZ9A	5688

1444 7590 03/24/2009

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EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
4121	

MAIL DATE	DELIVERY MODE
03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,649	BARENHOLZ ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11,13,14,16-20,26 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8,10,11,13,14,16-20,26 and 54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claim(s) 1-8, 10-11, 13-14, and 16, drawn to a lipid assembly comprising a phospholipid.

II. Group II, claim(s) 1-8, 10-11, 13, and 17-18, drawn to a lipid assembly comprising a monocationic lipid.

III. Group III, claim(s) 1-8, 10-11, 13, 17, and 19-20, drawn to a lipid assembly comprising a polycationic lipid.

IV. Group IV claim(s) 26, drawn to a pharmaceutical composition.

V. Group V, claim 54, drawn to a method for the treatment or prevention of a disease.

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule

13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Groups I-V is a lipid assembly comprising a biologically active lipid and a lipopolymer. The lipid assembly of claim 1 does not present a contribution over the prior art. As disclosed in Unger et al. (US Patent 5,585,112) the lipid assembly of instant claim 1 is not novel.

Unger et al. (US Patent 5,585,112) (hereafter referred to as Unger) teaches, in claim 3, a liposome comprising lipids selected from a group of biologically active lipids. Claim 3 does not explicitly state that the atomic mass ratio between the headgroup and hydrophobic region is less than 0.3; however, according to claim 3 of Unger, said biologically active lipids may be sphingolipids, reading on the lipids of instant claim 5. Therefore, the examiner asserts that the lipids of c–im 3 of Unger read on the biologically active lipid of instant claim 1.

Unger, claim 3, also teaches the presence of polymerized lipids. When read in light of column 24 lines 52-56, it is evident that said lipids may be PEGylated lipids. While Unger does not explicitly state that the lipids have an atomic mass ratio between the headgroup and hydrophobic region of at least 1.5, the examiner asserts that this is the case because instant claim 11 states that the polymer headgroup may be polyethylene glycol. Hence, the PEGylated lipids of Unger read on the lipopolymer of instant claim 1.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). As such, the fact that said lipid assembly being chemically and physically stable under storage conditions of 4 degrees Celsius in biological fluids is an inherent characteristic of the non-novel composition of instant claim 1. The burden is shifted to applicant to show that the stability possessed by the lipid assembly of instant claim 1 is not present in the composition of Unger.

As such, Group I does not share a special technical feature with the instant claims of Group II-V. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-V is broken.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- If Group I is elected, EACH of the following species elections are required:
    - *Biologically Active Lipid:* (e.g. N,N-dimethylsphingosine, ceramide, ceramine, sphinganine etc.) with claims 1, and 5-8 reading upon this species. Applicant must elect one specific biologically active lipid or one specific mixture of biologically active lipids.
    - *Lipopolymer:* (e.g. polyethylene glycol, polysialic acid, polyacetic acid) with claims 1, 10-11 and 13 reading upon this species. Applicant must elect one specific lipopolymer, or one specific mixture of lipopolymers.
    - *Phospholipid* (e.g. phosphatidylglycerol, phosphatidylcholine, phosphatidic acid etc.) with claim 16 reading upon this species.
- If Group II is elected, EACH of the following species elections are required:
    - *Biologically Active Lipid:* (e.g. N,N-dimethylsphingosine, ceramide, ceramine, sphinganine etc.) with claims 1, and 5-8 reading upon this

species. Applicant must elect one specific biologically active lipid or one specific mixture of biologically active lipids.

- *Lipopolymer:* (e.g. polyethylene glycol, polysialic acid, polyacetic acid) with claims 1, 10-11 and 13 reading upon this species. Applicant must elect one specific lipopolymer, or one specific mixture of lipopolymers.

- *Monocationic lipid* (e.g. 1,2-dimyristoyl-3-trimethylammoniumpropane, 1,2-dioleyloxy-3-(trimethylamino)propane etc.) with claim 18 reading upon this species.

- If Group III is elected, EACH of the following species elections are required:

  - *Biologically Active Lipid:* (e.g. N,N-dimethylsphingosine, ceramide, ceramine, sphinganine etc.) with claims 1, and 5-8 reading upon this species. Applicant must elect one specific biologically active lipid or one specific mixture of biologically active lipids.

  - *Lipopolymer:* (e.g. polyethylene glycol, polysialic acid, polyacetic acid) with claims 1, 10-11 and 13 reading upon this species. Applicant must elect one specific lipopolymer, or one specific mixture of lipopolymers.

  - *Polycationic lipid* (e.g. DOSPA, CCS) with claims 19 and 20 reading upon this species.

- If Group IV is elected, EACH of the following species elections are required:

- *Biologically Active Lipid:* (e.g. N,N-dimethylsphingosine, ceramide, ceramine, sphinganine etc.) with claim 26 reading upon this species.
- *Lipopolymer:* (e.g. polyethylene glycol, polysialic acid, polyacetic acid) with claim 26 reading upon this species.

- If Group V is elected, EACH of the following species elections are required:
  - *Biologically Active Lipid:* (e.g. N,N-dimethylsphingosine, ceramide, ceramine, sphinganine etc.) with claim 54 reading upon this species.
  - *Lipopolymer:* (e.g. polyethylene glycol, polysialic acid, polyacetic acid) with claim 54 reading upon this species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. As to claims 1-8, 10-11, 13-14, 16-20, 26, and 54, Applicant is required to elect a single term from the possibilities recited by said claims. Upon Applicant's election of species, the result must provide a single chemical species and a single condition or disease to be treated or improved. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are

added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- The following claim(s) are generic:
    - Claim 1 is generic to Group I.
    - Claim 1 is generic to Group II.
    - Claim 1 is generic to Group III.
    - Claim 26 is generic to Group IV.
    - Claim 54 is generic to Group V.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each chemical species is a distinct chemical which lacks a special technical feature in view of Unger et al. (US 5,585,112) (Column 25, Lines 30-37).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Joint Inventors and Rejoinder

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on Monday - Thursday 7:30AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 4121

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4121